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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,068	11/14/2003	Meng Yang	312762002710	2630

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EXAMINER
QIAN, CELINE X

ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
06/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,068	YANG ET AL.	
	Examiner	Art Unit	
	Celine X. Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-23,26,28,29,37,39 and 40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-23,26,28,29,37,39 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 20-23, 26, 28, 29, 37, 39 and 40 are pending in the application.

This Office Action is in response to the Amendment filed on 4/9/07.

Response to Amendment

The rejection of claims 24, 30-34 under 35 U.S.C. 112 2nd paragraph is moot because the claims are canceled.

The rejection of claims 20-23, 28, 29 and 37-38 under 35U.S.C.102 (b) is maintained for reasons set forth of the record mailed on 9/28/06 and further discussed below.

The rejection of claims 20-23, 26, 28, 39 and 40 under 35 U.S.C. 112 1st paragraph is maintained for reason set forth of the record mailed on 9/28/06 and further discussed below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-23, 25-29, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Contag et al (US 5,650,135, see IDS).

In response to this rejection, Applicants argue that Contag does not mention the use of assessing expression of an endogenous promoter. Applicants further assert that fluorescent proteins were never used by Contag since it teaches the use of a luciferase system that requires co-factors and substrates. Applicants further argue that the detection methods described by Contag do not include the required whole body external fluorescent optical imaging. Applicants

indicate that the description that follows and extends from col. 15 to col.17 involves photon counting, not fluorescent optical imaging. Applicants thus conclude that the Contag reference does not anticipate the instantly claimed invention.

This argument has been fully considered but deemed unpersuasive. The reasons for this rejection were set forth in detail in the previous office action. In response to Applicant's argument with regard to use of an endogenous promoter, it is apparent that the teaching of the Contag anticipates the limitation of "a promoter of an endogenous gene associated with said disease or disorder" because Contag et al. teaches that promoter may be the ones that are expressed in cells targeted by therapeutic gene (see for example col.12, lines 20-28, and col.14, lines 58-61). Unless the promoter is synthetic, ie. a hybrid promoter, the promoter will have to be isolated from an endogenous gene. As such, the teaching of Contag anticipates this limitation. In response to Applicant's argument with regard to whole body fluorescent imaging, it is rather clear from the teaching of Contag that fluorescent protein may be used instead of luciferase (see col.9, lines 29-40). It is quite clear when a fluorescent protein such as GFP is used (see col.9, lines 29-40) is used, measuring fluoresce would be used instead of photon emitting. The teaching of the entire reference encompasses that use of autofluoresce protein such as GFP, although luciferase were given an example of the invention, it does not exclude that use of autofluorecent protein. Therefore, for reasons set forth in the previous office action and above, this rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-23, 26, 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to this rejection, Applicants argue that the disease-associated promoters are known in the art, and the invention does not need to identify promoters that are associated with diseases. Applicants further assert that any screening results would be unpredictable.

The above arguments are fully considered but deemed unpersuasive. The reasons for lack of adequate description of the claimed invention were set forth in detail in the office action mailed on 9/28/06. The examiner wish to clarify that the rejection is not based on how to identify a promoter that is associated with a certain disease, rather, the lack of adequate description of the so called "disease-associated promoter" and its relationship on screening compounds for a candidate protocol. Depends on the definition, the disease associated promoter encompasses a large genus of promoter that either directs the expression of a gene that causes the disease, a gene that is expressed in a cell which has a diseased phenotype, or promoter from any bacteria, virus or other microorganisms that causes disease. In view such a broad genus of the promoter encompassed by the instant claim, in which the screening test is largely depends on such promoter's ability to direct expression of a gene in a whole animal (including transgenic animals), and the change of expression due to an externally administered compound which would result in the detectable change by whole body fluorescent imaging, the instant

specification would have be describe a representative number of claimed invention (the method using the promoter, not just "disease associated promoter" by its complete structure (ie. method steps) or other identifying characteristics (ie. what are the relevant characteristic for the claimed invention to work as it intended to). Since the specification fails to do both, the description of the claimed invention is not adequate. Therefore, for reasons set forth in the previous office action and above, this rejection is maintained.

Claims 39 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to this rejection, Applicants argue that there is not requirement for a working example for the enablement of the claimed invention. Applicants assert that method for producing a transgenic animal is well-known and are outlined in the application. Applicants further assert that "the change in intensity of the fluorophore may be the result of interaction with other gene products" is a rare event because the autofluorescent protein has been used in reporter gene methods for many years. Applicants thus conclude that the invention is enabled.

The above argument has been fully considered but deemed unpersuasive. The reasons for the non-enablement of the invention were discussed in detail in the previous office action. The rejection is not based on a single factor, lack of working example, but a combination analysis of wands factors including the nature of the invention, the breadth of the claim, the teaching of the specification and the state of art and the level of predictability in the art. The examiner does not mean the claimed screening method has be to fool proof, the statement with regard to interaction

with other gene product is just an example for unpredictability exists in the art of transgenic art. Although methods of making transgenic animals are known in the art, a transgenic animal that has a certain phenotype is result from trail and error, not routine experimentation. Further, in an whole animal system, whether the change in the fluorescent signal is due to the compound has an effect on the promoter itself is rather unpredictable for reasons such as drug interaction and metabolism. In view lack of teaching from the prior art and the unpredictability existed in the art, the specification need to provide teaching that would overcome such unpredictability in the art. However, the specification fails to do so. Therefore, the rejection is maintained for reasons discussed in the previous office action and above.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN, PH.D.
PRIMARY EXAMINER